

MANUFACTURING PROCEDURE FOR PRODUCTION TESTING OF X-RADIATION

DOCUMENT IDENTIFIER: A-SP-ELMF119-02-0 Rev A1, 19-May-1989

ABSTRACT:

This document describes:

- Production test criteria needed to fulfill the X-ray approval stipulations.
- Legal and X-ray approval requirements.
- Testing, record keeping, and reporting responsibilities.
- Sampling, test conditions, and labeling requirements.

APPLICABILITY: Mandatory for all manufacturing processes that produce cathode ray tube products with anode voltages of more than 20 kV and for all video displays capable of receiving an RF modulated video signal (VHF or UHF). For example, most high resolution monitors, color monitors, and television receivers are included.

Applicable to product safety, product assurance, manufacturing quality assurance, and purchasing engineers; design review committees; and product groups.

STATUS: APPROVED 19-May-1989; type \$VTX SMC for expiration date.

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REVISION HISTORY:	Rev. A,	15-Mar-1987	Initial Release
	Rev A1,	19-May-1989	ECO CTS01
Document Management Category:	Product Safety (HRS)		
Responsible Department:	Corporate Product Safety and Regulations		
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APPROVAL: This document is approved for use throughout Digital.

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MLO4-2/T65, DTN: 223-4424

JVAX::JOHNSON

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1 INTRODUCTION

This document is the corporate policy and process for X-radiation production testing, record keeping, and data reporting for monitors (monochrome and color) designed, manufactured or purchased for resale by Digital.

Testing is required for these products and conditions:

1. Monitors containing cathode ray tubes (CRTs) operated with more than 20 kV anode voltage are to be certified and approved per the West German X-ray Ordinance. This situation is normally found in:
 - Monochrome CRT monitors with 19 inches or greater diagonal measurement.
 - Color CRT monitors with 14 inches or greater diagonal measurement.
2. CRTs that receive a modulated radio frequency signal (UHF or VHF) and are sold in the U.S. or Canada.

All monitors intended to be offered for sale under the above conditions must comply with the requirements of this document.

Compliance with this document implies that the design and production of the product meets the requirements of the relevant sections of this document.

1.1 SCOPE

This document includes information concerning X-ray and anode voltage relating to mandatory:

- Production measurements.
- Record keeping and reporting processes.
- Marking requirements.
- Provisions of the X-ray approval certificate.

This document also provides requirements and responsibilities to:

- Prevent problems that might adversely affect the X-ray approval status and operating requirements of monitors.
- Ensure that all monitors meet the X-ray approval requirements set by regulatory authorities.
- Ensure that all monitors marketed by Digital can be operated in markets with regulatory authorities.

1.2 IMPLEMENTATION

The responsible Product Safety Engineer assigned in Phase 0 or 1 of the Phase Review Process shall notify Manufacturing Product Safety and Regulations (MPS&R) and the appropriate Plant Product Safety Coordinators (PPSCs) that the product requires production testing.

Needed test equipment as described in subhead 3.3 must be available and test personnel must be assigned before production startup.

Manufacturing test personnel must have a copy of this document available.

The required testing process must be followed on all production runs. Reports are to be filed quarterly to MPS&R.

Test data shall be centrally collected and maintained, and reports shall be forwarded to country representatives as required by subhead 3.6.

2 X-RADIATION REGULATIONS

2.1 WEST GERMAN X-RAY ORDINANCE REQUIREMENTS

The West German X-ray Ordinance states that all sources of spurious X-rays (ionizing radiation) that have an anode voltage of greater than 20 kV, generally all color monitors, be submitted for product certification and subsequent approval.

In accordance with the X-ray approval requirements, the manufacturer must subject the units to ongoing production testing and retain records to verify that products comply with the requirements of the approval. This is essential for X-ray shielding.

Per the West German X-ray Ordinance and the safety regulations of electrically energized office equipment (VDE 0806), equipment that produces ionizing radiation shall, at any accessible point 5 cm from the outer surface, emit less than 5 uSv/h (0.5 mR/h).

2.2 U.S. RADIATION CONTROL ACT

United States law, 21 CFR Subchapter J, requires X-ray emissions to be below 5 uSv/h (0.5 mR/h). Also, production testing and reporting is required for television products, interpreted to include monitors or CRTs that receive a modulated radio frequency signal (UHF or VHF).

2.3 CANADIAN RADIATION EMITTING DEVICES ACT

The Radiation Emitting Devices (RED) Act requires X-ray emissions to be below 5 uSv/h (0.5 mR/h). Currently, no requirements exist for production testing and reporting. Inspectors may at any reasonable time enter the premises of a manufacturer and examine devices, open products, and examine books, reports, records, and other information if he or she believes them to contain information or products relative to the enforcement of the Act. Such an inspection has only occurred once at Digital. The appropriate people, as discussed in this document, should be called upon to assist in such an inspection.

2.4 IEC STANDARDS

There are no production testing requirements in International Electrotechnical Commission (IEC) standards for X-ray producing products. There is, however, a requirement that products not exceed an X-ray emission level of 5 uSv/h (0.5 mR/h). This requirement is in IEC 380, IEC 435, and IEC 950.

2.5 DIGITAL STANDARD 119-1

DEC STD 119-1, subhead 1.11.1, requires X-radiation emission to be no more than 2 uSv/h (0.2 mR/h). It is this level that is tested for in this document. While higher levels are permitted by other standards, anything in excess of this level indicates a lack of controls and is cause for further investigation. Normal levels generated are much lower than this, and, in fact, are indistinguishable from normal background radiation.

3 PRODUCTION X-RAY TESTING PROCESS

3.1 MEASUREMENT

These tests are to be done after the unit is electrically functional and adjusted. They are usually done before final assembly of the enclosure.

3.1.1 Anode Voltage Test

Follow these steps to accomplish the anode voltage test:

1. Remove covers to allow access to the CRT anode clip.
2. Operate the product at the nominal line voltage as specified by the product label. In the case of dual voltage equipment, use the upper voltage. For example, use 240 V if the product is labeled 120/240 V.
3. Measure the voltage at the anode clip on the CRT with respect to earth ground (or a point called out in the engineering drawings in the case of Class II or double-insulated equipment).
4. Adjust any operator accessible contrast and brightness controls for maximum anode voltage. (These are controls accessible to the user under normal operating conditions with the covers installed.)
5. Make sure the maximum anode voltage does not exceed the approved maximum anode voltage. Reject the product if excessive readings are observed; then repair the product.
6. Record the maximum anode voltage, model number, serial number, and date (including any with excessive readings).
7. Disconnect meter, replace covers, and proceed to the radiation emission test; or reset, if necessary, any controls and voltage select switch.

3.1.2 Radiation Emission Test

Follow these steps to accomplish the radiation emission test:

1. Select units for test based on the sample selection criteria (subhead 3.2). Perform testing on all surfaces (top, all sides, and bottom) except as noted in subhead 3.2b, exception 2.
2. Operate the product at the nominal line voltage as specified by the product label. In the case of dual voltage equipment, the upper voltage selection is used. For example, 240 V if the product is labeled 120/240 V.
3. Scan the product for measurable radiation using the manufacturer's operating instructions for the X-radiation meter. The detector size and scan rate determine the speed and sweep pattern needed to test the product.

NOTE

Take the measurement 5 cm from the surface. This usually means the instrument is placed directly against the outer surface of the product because that places the center of the detector 5 cm from the product surface.

4. Make sure the measured value does not exceed 2 uSv/h (0.2 mR/h). Any excessive readings shall be reported to manufacturing engineering and to the Plant Product Safety Coordinator. The Plant Product Safety Coordinator shall contact Field Service Product Safety for further investigation and corrective action.

5. Record the maximum radiation measurement from the product (or the threshold not exceeded), the area scanned, model number, serial number, and date (including any excessive readings).
6. Reset, if necessary, any controls and voltage select switch.

3.2 SAMPLE SELECTION CRITERIA

Use the following information to determine the sample size:

- a. All products (100% of production) are subjected to the Anode Voltage Test (subhead 3.1.1).
- b. All products (100% of production) are subjected to the Radiation Emission Test (subhead 3.1.2).

Exception 1: If no value measured during past production exceeds 2 uSv/h (0.2 mR/h), the Radiation Emission Test (subhead 3.1.2) shall be conducted on 5% (minimum) of the total units.

Exception 2: If no value measured during past production exceeds 1 uSv/h (0.1 mR/h), the Radiation Emission Test (subhead 3.1.2) shall be conducted on all surfaces of 0.5% (minimum) of the total units, and additionally, shall be conducted on the front side only of 4.5% (minimum) of the total units.

NOTE

There is no required sample size that must meet the maximum requirement of 2 uSv/h (0.2 mR/h) or 1 uSv/h (0.1 mR/h) before the sample plan can be used. Production testing can start directly with the sampling plan.

Digital's test history with monochrome and color monitors over the last 10 years indicates that X-ray levels are very low, in the range of 0.2 uSv/h (20 uR/h), which is considered to be in the "background" level. Therefore, it is sufficient to use the sampling ratio.

3.3 PRODUCTION TEST EQUIPMENT

Refer to Appendix B for a list of acceptable production test instruments.

3.3.1 High Voltage Meter

The instrument must have an input impedance of 100 Mohms minimum, an accuracy better than 3%, and a range of 40kV dc. A digital-readout meter is preferred to reduce reading errors. See Appendix B for acceptable equipment.

Certified calibration shall be done at least yearly.

3.3.2 X-radiation Meter

The instrument must be an X-radiation (gamma) detector with a sensitivity of 0.5 uSv/h (0.05 mR/h), response time less than 90% within 12 seconds, have energy response down to 12 Kev, and shall be designed for use in CRT X-radiation measurements.

Calibration shall be done against built-in or accessory sources as recommended by the manufacturer with a certified laboratory calibration done at least yearly.

3.4 READING METHODS

Two methods can be used to measure the X-ray emission levels in production that satisfy the approval requirements:

- a. Actual readings
- b. Go/no-go readings

Digital's monitors, as typically designed, measure such a low reading that the actual radiation level is considered environmental noise. Therefore, measuring the actuals is not very useful. If the test equipment is set to respond to a very low threshold, such as 0.2 uSv/h (20 uR/h), the recorded test data can state: "less than 0.2 uSv/h (20 uR/h)" (go/no-go reading method).

3.5 RECORD KEEPING

Recorded results of the production dose rate measurements shall include:

- Name and address of manufacturer
- Equipment model and serial numbers
- CRT model and serial numbers
- X-ray approval number
- Anode voltage test results
- Radiation emission test results
- Production and test quantity
- Production and/or test dates
- Test equipment used
- Test method used
- Name, location, and signature of inspector

The reports shall be forwarded to Manufacturing Product Safety and Regulations for filing and forwarding to the appropriate country representatives and approvals authority.

Reports shall be archived by Manufacturing Product Safety and Regulations for at least five years.

3.6 REPORT SUBMISSION

Copies of the quarterly production X-ray reports shall be forwarded each quarter to the Country Representatives for use in local reporting.

The U.S. NCDRH report shall be filed annually as described in Appendix D.

3.7 EQUIPMENT MARKING AND PROVISION OF APPROVAL CERTIFICATION

The product must be labeled in accordance with the latest revision of DEC STD 178-3, subhead 10. A copy of the approval certificate and test confirmation must be included in accordance with DEC STD 119-1, subhead 1.14.

It must be ensured that the measured anode voltage does not exceed the limit published in the test confirmation document noted above.

4 RESPONSIBILITIES

4.1 DIGITAL-MANUFACTURED PRODUCTS

Digital, as manufacturer and approval owner, must subject its products to ongoing routine testing in production.

Corporate Product Safety shall ensure that a process exists and is followed for performing X-radiation testing and reporting.

Design product safety engineers shall notify Manufacturing Product Safety and Regulations and the appropriate Plant Product Safety Coordinator that the product requires testing. This must be done in phase 0 or 1 of the phase review process.

The Plant Product Safety Coordinator shall ensure that:

- Required testing is performed.
- Required test data is provided to Manufacturing Product Safety and Regulations within a month of each quarter ending.
- Proper labeling and certificates accompany the product (see subhead 3.7).
- Test results do not exceed the limits of the test criteria in subhead 3, the limits of DEC STD 119-1, subhead 1.11.1, and the conditions of the certification published at the direction of DEC STD 119-1, subhead 1.14.

Manufacturing Product Safety and Regulations shall:

- Ensure that needed test equipment is available.
- Ensure that test personnel are assigned.
- Ensure that, in the case of a Digital-purchased product, an equivalent function to the PPSC is performed to assure needed testing and reporting is performed.
- Ensure that the reporting process and procedure for reporting the X-ray production test data to the local representative exists and is functioning properly. This process must allow for a quick response to the approval authority when test data is requested.
- Collect the incoming report data.
- Maintain the data in a central file and distribute the data electronically in the standardized form as shown in the sample report in Appendix A.
- File the annual report with the NCDRH as described in Appendix D by September 1 after the end of each fiscal year.

The West German country representative shall:

- Maintain a file of all reports for products that have passed the PTB certification type testing and have subsequently been approved by the approvals authority.

- Make reports available to the approvals authority when the the data is requested.

U.S. country representative duties are to be done by Manufacturing Product Safety and Regulations as described above.

4.2 BUYOUT PRODUCTS

For buyouts, the obligation for X-radiation production testing shall be delegated by Digital to the vendor. Digital's development or purchasing group, responsible for bringing the product into Digital, shall designate a representative to ensure, with the support of Corporate Product Safety, that:

- A production test process and the subsequent record keeping and reporting process is established and maintained in the vendor's production plant.
- A clause exists in the purchase contract to require that ongoing X-radiation production testing, record keeping, and reporting be done.

APPENDIX A

EXAMPLE OF AN X-RAY PRODUCTION TEST RECORD

This report contains fictional information.

This report form is a comprehensive set of production dose rate measurement data designed to satisfy the requirements from the West German X-ray approval authority in a format that permits comparison to products from different color monitor manufacturers. It is used by Manufacturing Quality Assurance, Corporate Product Safety, and Digital's country representative to submit production test data to the X-ray approvals authority when requested.

A.1 X-RAY PRODUCTION SAMPLING TESTING

Model:VR241-A Approval No: By 263/83/Ro Equipment Manufacturer: Digital Equipment Corporation CRT: Hitachi 370RCB22

Period of production: 1-Jan-85 to 31-March-85 Production quantity: 532 units (total)

sampling ratio, total: 5% (27) sampling ratio, front: 90% from total (24) sampling ratio, all sides: 10% from total (3)

Test condition: Anode voltage adjusted to nominal 24.5 kV during measurement, external contrast and brightness controls at maximum, normal operating conditions.

Test equipment: Dose Ratemeter "TOL/E" Laboratorium Professor Dr. Berthold, High voltage meter, Brandenburg 88M.

No.	Equipment Ser. No.	CRT Ser. No.	Manufac. Date	Front	Back	Right	Left	Bottom	Anode (KV)
1	Y3J002426	M2K396439	14/01/85	*	—	—	—	—	
2	Y3J002427	M2K396445	15/01/85	*	*	*	*	*	
3	Y3J002428	M2K396451	16/01/85	*	—	—	—	—	
4	Y3J002429	M2K396454	17/01/85	*	—	—	—	—	
5	Y3J002430	M2K396455	18/01/85	*	*	*	*	*	
6	Y3J002431	M2K396462	19/01/85	*	—	—	—	—	
7	Y3J002432	M2K396463	20/01/85	*	—	—	—	—	
27	Y3J002452	M2K396488	25/03/85	*	—	—	—	—	

NOTE

Asterisk (*) indicates X-radiation is less than 2 uSv/h (0.2 mR/h).

Measuring Production Inspection Section:

Signature _____

Printed Name: _____

APPENDIX B

ACCEPTABLE PRODUCTION TEST EQUIPMENT

B.1 HIGH VOLTAGE METER

Simpson model 360-2 DVM with No. 00432 High Voltage Probe

Fluke Model Series 8020, Series 860, Series 70, Model 8050A, Model 8010A or Model 8012A; with Model 80K-40 High Voltage Probe.

B.2 X-RADIATION METERS

The following X-radiation meters have been found acceptable by U.S., Canadian, and West German authorities and are used for production testing by other EDP or video equipment manufacturers.

B.2.1 Portable X-ray Dose Rate Meter (Model number 'TOL/E'):

This meter includes a calibration capability and is made by:

Laboratorium Professor Dr. Berthold,
Postfach 160
D-7547 Wildbad 1
West Germany
Tel. 07081/3981

The United States representative is:

Berthold Analytical Instruments, Inc.
28 Charron Avenue
Nashua, NH 03063
Tel. (603)-889-3309, (800)-343-6345

The meter can be operated by mains or independently through a built-in rechargeable battery. It has a very wide measuring range from background noise up to higher dose rates.

B.2.2 Victoreen Model 440 RF/C

The Victoreen (Model 440 RF/C) is a radiation survey meter designed specifically for CRT X-ray emission measurements. It gives a reading down to 0.1 mR/h. It has a detector of the geometry and dimensions required by the standards. It has a scan width of only 1.4 inches and a maximum scanning rate of 2 ft/min, meaning a complete product scan can take up to an hour, not a practical production exercise, but acceptable for type tests and to give verification of true level from hot spots detected by threshold type meters. It is battery powered by four D cells and one 22.5V No.412 battery. Available from:

Victoreen Instruments
10101 Woodland Ave
Cleveland, Ohio 44104
Tel. (216)-795-8200

B.2.3 E.F. Johnson Model TV150

The E.F. Johnson Model TV150 is a scanning threshold instrument. It is useful for detecting radiation, but not in quantitatively measuring it. As such, it is usually used with a meter such as the Victoreen 440RF/C. This meter is an array of GM tubes, which in a single pass over the sides of a product, indicates the presence or absence of detectable radiation.

APPENDIX C

RELEVANT WEST GERMAN INFORMATION

C.1 MARKET SURVEILLANCE

The approvals authority is entitled to request individual units of its own choice from Digital's country representative in order to test them or have them tested for features essential as regards X-ray shielding.

NOTE

It is likely that the approvals authority will take samples from the West German marketplace to verify Digital's production testing. The approvals authority has no intent or right to visit the manufacturing inspection section at the point of manufacture.

C.2 WEST GERMAN X-RAY CERTIFICATION AGENCY

According to the West German X-ray Ordinance, the only recognized certification testing agency for sources of spurious X-ray is the:

RELEVANT WEST GERMAN INFORMATION

Physikalisch-Technische Bundesanstalt (PTB)

Postfach 335

Department 6.62

Mr. Lauterbach or Mr. Balke

Bundesallee 100

D-3300 Braunschweig

West Germany

Tel. 0531/592(1)-6620

Digital's country representative arranges for a submittal to the PTB. The submittal will take place in PTB's test laboratory in Braunschweig, West Germany, or exceptionally at the local applicants site. After product certification testing, PTB will automatically send one test certificate to the X-ray approvals authority and one test certificate to the applicant (Digital West Germany).

The test certificate contains the maximum anode voltage and beam current under normal operating conditions. Type testing is not carried out under worst case conditions (as in the United States).

C.3 WEST GERMAN X-RAY APPROVAL AUTHORITY

The West German authority used by Digital West Germany to obtain X-ray approvals is:

Bayrisches Staatsministerium fuer Arbeit und Sozialordnung (StMAS) (Bavarian state ministry for labor and social welfare).

Postfach 132
Department II-Referat 5
Mr. Wilhelm or Mr. Hoffman
Winzererstr. 9
D-8000 Muenchen 40
West Germany
Tel. 089/1261-1388

An approval is granted by the StMAS when requested by the applicant and when type tested previously by the PTB. The approval issued by the Bavarian StMAS is valid throughout West Germany.

C.4 DIGITAL'S COUNTRY REPRESENTATIVE

In accordance with the X-ray approval requirements, a local COUNTRY REPRESENTATIVE (competent specialist) must be assigned to interface with Digital's development and manufacturing organizations to monitor production testing. Digital's formal local representative for the approval authority is Horst Kuhn, Product Marketing/Product Assurance Manager in Munich, West Germany. All contacts to the authority will be made by him.

When not available, Horst Kuhn's office, or the European Product Safety Manager in Geneva (Fred Pieters), will support your needs.

Because the country representative cannot possibly be at all manufacturing sites, he or she has to delegate responsibility to ensure compliance with approval requirements to the Manufacturing Quality Assurance and Corporate Product Safety Managers. There is no need, nor a requirement, to notify the approvals authority of this delegation. The country representative remains responsible. However, the country representative must have a list of people that monitor the product/process compliance issues.

APPENDIX D

FILING OF ANNUAL REPORTS, U.S. NCDRH

The procedure described in the National Center of Devices and Radiological Health (NCDRH) document, Guide to Preparing Annual Reports on Radiation Safety Testing of Cathode Ray Tubes, 1973, should be used by Manufacturing Product Safety and Regulations to prepare and file reports.

This Appendix provides instructions for completing the required form (subheads D.1.1 through D.1.6) and shows the six-part form (pages 22 through 26).

D.1 INSTRUCTIONS FOR COMPLETING THE FORM

D.1.1 Part 1 Manufacturer/Importer Identification

Fill in the requested information and sign where indicated. Fill in the years in the reporting period. Examples: The report due on September 1, 1983, should cover the reporting year July 1, 1982, through June 30, 1983.

Check the statement and fill in the report identification if you are submitting a supplement to an annual report.

D.1.2 Part 2 Production Status

Check the statement that applies to your firm and take the indicated action.

D.1.3 Part 3 Current Production and Test Results Tabulation

NOTE

CRTs operating under 15,000 volts need not be reported in an Annual Report, pursuant to 21 CFR Subchapter J, Section 1002.11.

Provide annual production data, using the form or a comparable tabulation. If additional space is needed, use another copy of the form or attach a separate sheet and label it Part 3.

"Accession No.": For previously reported models, NCDRH will have assigned this number and reported it to you.

"CRT Family Designation": Indicate the CRT family designation. This may be unique identification assigned to a family of CRTs to differentiate it from other CRTs produced by the same manufacturer. It may also be a tube type number for a tube representative of a given family. If a tube type number is used to identify a CRT family, this same number should be used in all future reference to this product type.

A CRT family consists of a group of one or more CRT types or selling model numbers which have the following characteristics:

1. Same screen size
2. Same display
3. Same deflection angle
4. Same X-radiation limit curves, registration reference points, and X-ray slope factors according to EIA or EIAJ for:
 - a. Entire tube (except anode contact)
 - b. Tube face only
 - c. Anode contact
5. Same maximum voltage difference between the anode and focus electrodes

"Total No. Produced" and Total No. Tested": Indicate the total number of tubes produced and tested within a given CRT family during the reporting period.

"X-Radiation": Measurements should be taken at the registration reference point voltage and the standard beam current used in developing the isoexposure curves. This current is 250 microampers for monochrome tubes and 300 microamperes for color tubes.

In the "Mean" columns, indicate the average of all measurement for any tube in the CRT family.

In the "Max" columns, indicate the highest measurement for any tube in the CRT family.

D.1.4 Part 4 Summary of Test Results

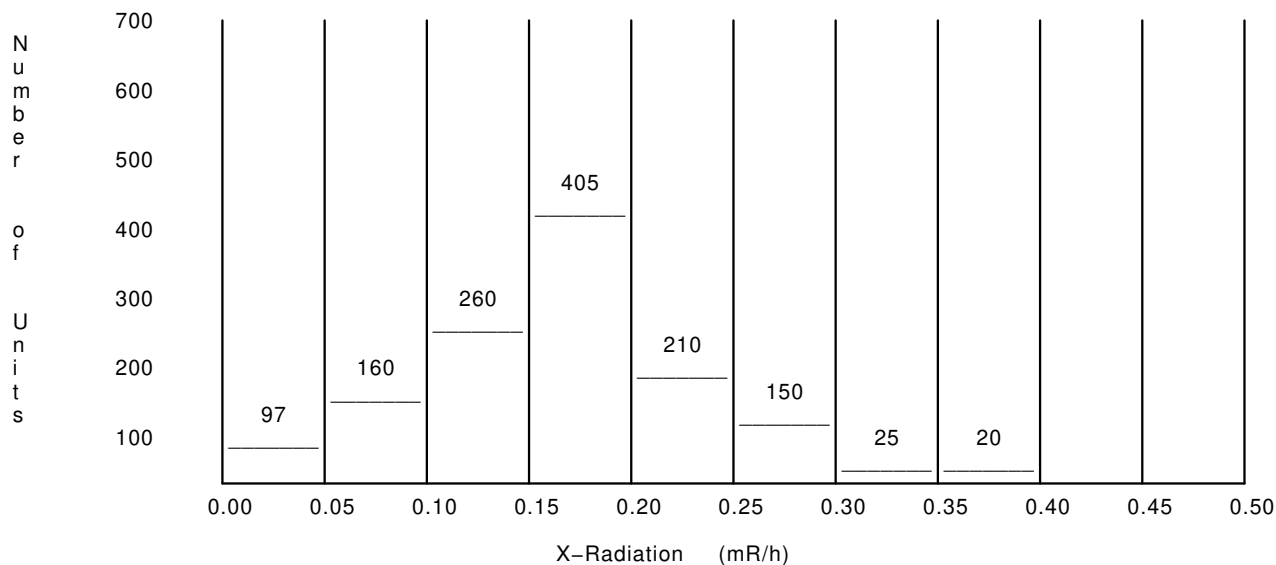
You are required by 21 CFR 1002.30(a)(2) to maintain results of quality control tests. For each product introduced into commerce, you should evaluate test results to be certain that the total program is adequate to assure radiation safety.

In addition to Part 3 requirements, when your test results are recorded as numeric values, provide a frequency distribution of X-radiation test data in the form of a graph or chart (or other suitable means to convey the same information). One acceptable method is given in the following example.

Example:

CRT Family: 61 cm, 100°, 20 mm, Condition: 35 kV at 300 uA

X-Radiation reject limit: 0.37 mR/hr



X-Radiation (mR/hr)

Maximum measurement: 0.37 mR/hr

D.1.5 Part 5 Procedures for Quality Control and Testing

You are required by 21 CFR 1002.30(a)(1) and (2) to maintain written procedures for quality control and testing. The procedures in use and those submitted in the initial or Model Change Reports should be reviewed and updated.

Compare your current procedures with those submitted in your Initial or Model Change Reports. Check the appropriate answers and take any indicated action.

D.1.6 Part 6 Correspondence Concerning Radiation Safety

You are required by 21 CFR 1002.30(a)(4) to maintain copies of communications to or from dealers, distributors, and purchasers concerning radiation safety. Correspondence should be reviewed if it involves any of the following: complaints or concerns about radiation exposure; difficulties with safety components in use or servicing of the product; investigations made or instructions made or instructions issued concerning use, adjustment, and repair.

Fill in the number of documents sent or received and attach the summaries or samples as indicated.

NOTE

This summary does not replace the notification requirements for potential defects or noncompliances under 21 CFR 1003.10 or for suspected accidental radiation occurrences under 21 CFR.

Part 1. Manufacturer/Importer Identification Report Date:

Manufacturer

Company Name:

Address:

The Annual Report is submitted in accordance with 21 CFR 1002.11 for the period July 1, 19__, through June 30, 19__.

() This is a supplement to Annual Report NCDRH Accession No. _____
submitted on _____.
(date)

Corresponding Official: _____
(signature)

(name) _____ (_____) _____
(title) (telephone)

Importer (Complete if applicable)

Company Name:

Corresponding Official: _____
(signature)

(name) _____ (_____) _____
(title) (telephone)

Part 2. Production Status

- Products were manufactured during this period and the firm is still in business. If you check this, complete and mail this entire report.
- No products were manufactured during this period, but the firm is still in business and expects to manufacture in the future. If you check this, complete Part 6 and mail pages 1 and 4.
- No products were manufactured during this period and the firm is now out of business. If you check this, complete Part 6 and mail pages 1 and 4.
- Products were manufactured during this period, but the firm is now out of business. If you check this, complete and mail this entire report.

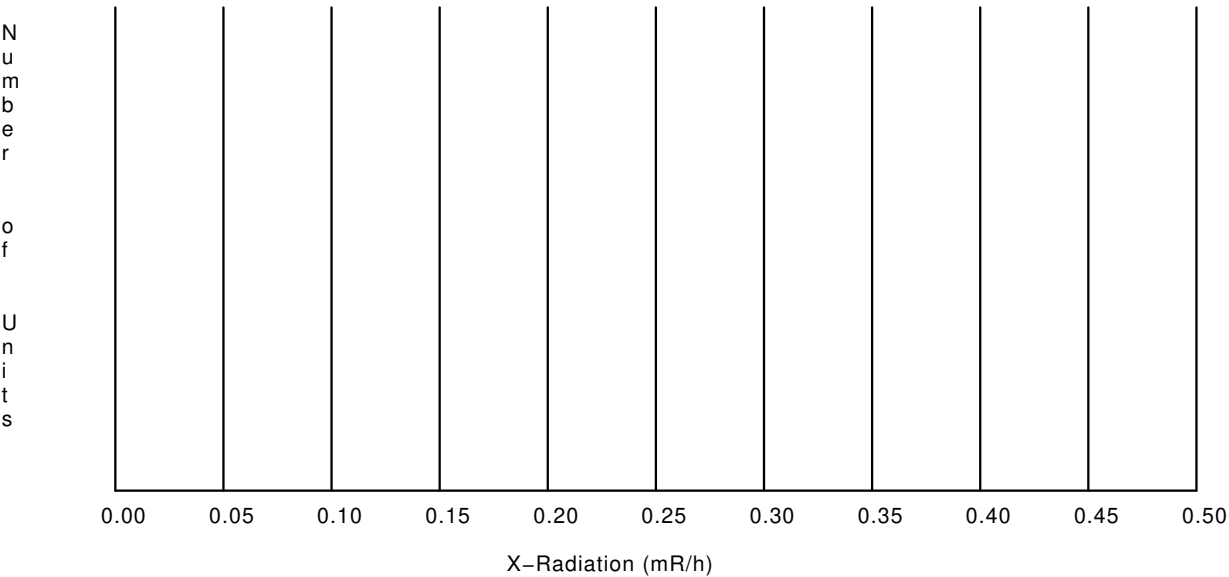
Part 3. Current Production and Test Results Tabulation

Accession No.	CRT Family Designation	Total No. Produced	Total No. Tested	X-Radiation (mR/h)			
				Face Plate Mean	Face Plate Max.	Entire Tube Mean	Entire Tube Max.

Part 4. Summary of Test Results

CRT Family: _____, Condition: _____ kV at _____ uA

X-Radiation Reject Limit: _____ mR/h

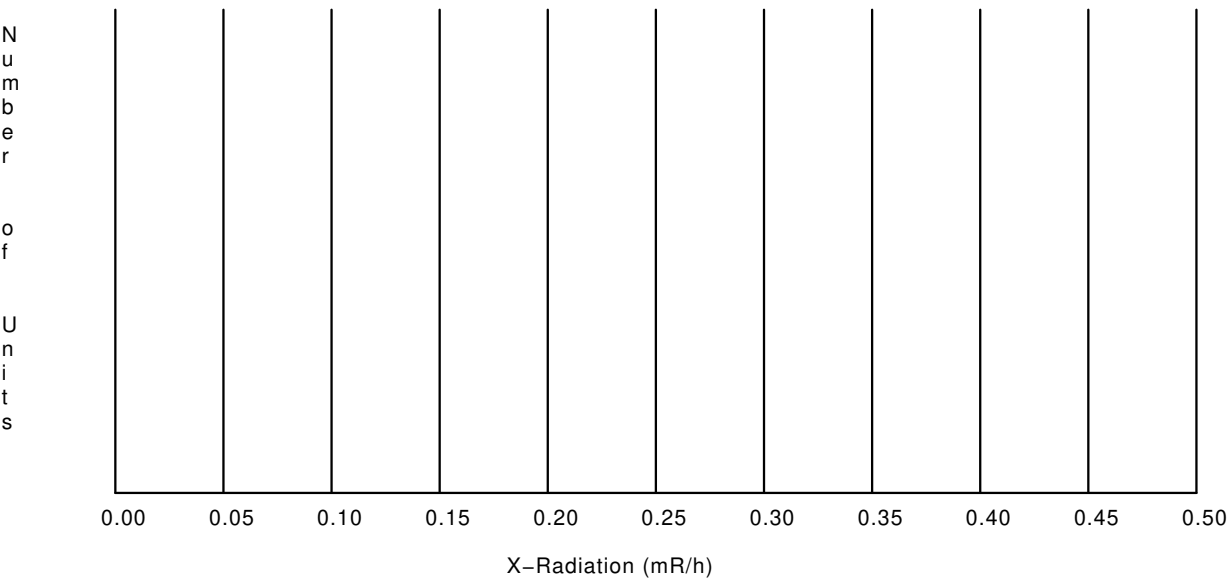


Maximum Measurement: _____ mR/h

=====

CRT Family: _____, Condition: _____ kV at _____ uA

X-Radiation Reject Limit: _____ mR/h



Maximum Measurement: _____ mR/h

Part 5. Procedures for Quality Control and Testing

The written procedures for assessing and controlling radiation safety have been reviewed. (These include prototype testing and incoming materials testing.) The procedures for maintaining quality control testing equipment have also been reviewed. All procedures are up-to-date, complete, and accurate. () Yes () No

The reports provided to NCDRH for each CRT family family currently in production have been reviewed and the procedures contained in them are up-to-date, complete, and accurate. () Yes () No

If you answered no to either question, attach the current procedures if they apply to all CRT types. If they apply only to a specific CRT family, provide the current procedures in a supplement to the appropriate CRT family Model Change Report.

Part 6. Correspondence Concerning Radiation Safety

The number of letters received from users, dealers, or others about possible radiation exposure during use of the product was _____ .

Attach a summary of correspondence.

The number of notices or brochures sent to users, dealers, or service personnel on precautions or actions to be taken to maintain radiation safety of the product was _____ .

Attach a summary of correspondence or a sample.

APPENDIX E

REFERENCED DOCUMENTS

E.1 EL-Class Digital Documents

EL-Class Number	Document Title
EL-00119-01	<i>DEC STD 119-1 Digital Product Safety Design Criteria</i>
EL-00178-03	<i>DEC STD 178-3 Digital Marking Requirements for Completed Products Intended to be Sold</i>

Copies of Digital EL-Class documents may be obtained from Standards and Methods Control, \$ VTX SMC, JOKUR::SMC, DTN: 234-4423, or NRO4/D4.

Please provide your name, mailstop, cost center, badge number, and node address when ordering.

E.2 Other Documents

Document Title
<i>Guide to Preparing Annual Reports on Radiation Safety Testing of Cathode Ray Tubes</i>

Copies of this document are available by calling (301) 443-3552 or writing to:

National Center for Devices and Radiological Health (HFX-28)

Rockville, MD 20857

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